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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,160	09/05/2000	Paul W. Sternberg	CIT1520-2	8179

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EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	17

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/655,160	STERNBERG ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22 and 25, drawn to a nucleic acid sequence encoding nematode PKD-2, a mutated form of same nucleic acid sequence, a vector encoding same PKD-2 nucleic acid sequence, a transgenic nematode comprising same PKD-2 nucleic acid sequence, a transgenic nematode comprising same mutated PKD-2 nucleic acid sequence, a method of identifying genes classified in classes 536, 435, and 800, subclasses 23.1, 320.1, and 13.

II. Claims 23-24, drawn to an isolated PDK-2 polypeptide, classified in class 530, subclass 350.

III. Claim 26, drawn to a LOV-1-PDK-2 protein complex, classified in class 530, subclass 402.

IV. Claims 27-30, drawn to a method of mutating LOV-1 or PKD-2 genes in a nematode, classified in class 435, subclass 441.

V. Claims 31-38, drawn to a method of treating a nematode with a compound that alters mating behavior, and method for identifying compounds that can alter mating behavior, classified in class 435, subclass 441.

VI. Claims 39-41, 43-46, and 48-51, drawn to a method for identifying genes which are part of the disease pathway of autosomal polycystic kidney disease, classified in class 435, subclass 6.

VII. Claims 42 and 47, drawn to a method for identifying compounds that are potentially therapeutic for treatment of polycystic kidney disease, classified in class 435, subclass 7.

VIII. Claims 54-61, drawn to a method of screening nematodes using bacteria, classified in classes 435 and 435 subclasses 441and 7.2.

IX. Claims 62-63, drawn to a mutant strain of nematode comprising a mutated PDK-2 gene, classified in class 800, subclass 8.

X. Claims 52-53, drawn to a method for identifying regulators and factors necessary for synthesis and transport of LOV-1 or PKD-2 protein, classified in class 435, subclass 7.1.

Inventions I and II-III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The nucleic acid molecule of invention I can be used to transform somatic cells in vitro and as a probe in a hybridization assay. The polypeptides of inventions II-III can be used as antigens to generate antibodies in a host. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized

divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I and (IV-VIII and X) are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The nucleic acid molecule of invention I can be used to transform somatic cells *in vitro* and as a probe in a hybridization assay. The methods of inventions VI-X can be practiced with materially different products from the nucleic acid of Group I. For example, the method of Group IV is directed to a method of mutating genes in a nematode, the method of Group V is directed to screening compounds in a mutated nematode, the method of Group VI is directed to a method of identifying genes, the method of Group VII is directed to a method of identifying compounds that can treat polycystic kidney disease, the method of Group VIII is directed to a method of screening nematodes, and the method of Group X is directed to identifying regulators and factors. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The nucleic acid

molecules of invention I can be used to transform somatic cells *in vitro* and as a probe in a hybridization assay. The mutant strain of nematode of invention IX can be used as a disease model. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II and III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Groups II and III are polypeptides that have different structures and functions. The protein of invention IV is a PKD-2 polypeptide. The polypeptide complex of invention III comprises the LOV-1 and PDK-2 polypeptides. Because these inventions are distinct for the reasons given above and separate searches are required for inventions II and III, restriction for examination purposes as indicated is proper.

Inventions (II-III) and (IV-VIII and X) are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The polypeptide of invention II can be used as an antigen to generate antibodies in an

animal. The methods of inventions IV-VIII and X can be practiced with materially different products from the polypeptide of Group II. For example, the method of Group IV is directed to a method of mutating genes in a nematode, the method of Group V is directed to screening compounds in a mutated nematode, the method of Group VI is directed to a method of identifying genes, the method of Group VII is directed to a method of identifying compounds that can treat polycystic kidney disease, the method of Group VIII is directed to a method of screening nematodes, and the method of Group X is directed to identifying regulators and factors. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II-III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not capable of use together. The polypeptide of invention II can be used as an antigen to generate antibodies in animal. The mutant strain of nematode of invention IX can be used as a disease model. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups IV-VIII and X because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. For example, the method of Group IV is directed to a method of mutating genes in a nematode, the method of Group V is directed to screening compounds in a mutated nematode, the method of Group VI is directed to a method of identifying genes, the method of Group VII is directed to a method of identifying compounds that can treat polycystic kidney disease, the method of Group VIII is directed to a method of screening nematodes, and the method of Group X is directed to identifying regulators and factors. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups IV-VIII and X restriction for examination purposes as indicated is proper.

Inventions IX and (IV-VIII and X) are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The mutant strain of nematode of invention IX can be used as a disease model. The methods of inventions IV-VIII and X can be practiced with materially different products from the polypeptide of Group II. For example, the method of Group IV is directed to a method of mutating genes in a nematode, the method of Group V is directed to screening compounds in a mutated nematode, the method of Group VI is directed to a

method of identifying genes, the method of Group VII is directed to a method of identifying compounds that can treat polycystic kidney disease, the method of Group VIII is directed to a method of screening nematodes, and the method of Group X is directed to identifying regulators and factors. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

A telephone call was made to Lisa Haile on 6/3/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER